

REMARKS

Claims 1-27 are currently pending in the present application. Claims 1, 18, 26 and 27 are amended herein. Claims 15-17 and 23 are cancelled, rendering their rejection moot. By this amendment, claims 1-14, 18-22, and 24-27 are pending.

Rejection of claims 18-27 under 35 U.S.C. §112, first paragraph

The Examiner rejects claims 18-27 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The office action asserts that the examples in the specification are only directed to the treatment of patients for vascular disease. The office action further asserts that it is unclear if the improvement of vascular disease was achieved due to the claimed composition or other treatments received, as the patients recited in the examples were undergoing treatment with other therapeutics. The office action further asserts that there is no evidence that the claimed methods are effective in preventing vascular disease and treating and preventing dementia.

Applicant respectfully asserts that the terms “treatment and prevention” are defined on pages 13 and 14 of the patent application. On page 13, treatment of a disease is defined in the last paragraph as not requiring a cure of the disease. An effective amount is defined as an amount capable of reducing the severity or occurrence of one or more conditions associated with a particular disease. On page 14, second paragraph, prevention of vascular disease is described as including a reduction in the onset or severity of vascular disease by administering a novel vitamin composition of the present invention. On page 14, third paragraph, it is disclosed that any of the vitamin compositions described in the application may be administered to an individual having a vascular disease or dementia.

With regard to the specific examples, and the statement that there is no evidence that the claimed methods are effective in the absence of other compounds, Applicant respectfully emphasizes that several of these examples describe patients currently receiving some form of

therapy. The claimed vitamin composition described in Example 1 is then administered to the patient and its effects are reported. In Example 2, the first patient demonstrates a decrease in vascular disease in the graft vessels following administration of the vitamin composition. The second patient in Example 2 demonstrates decreased arrhythmic episodes following administration of the vitamin composition. Further, Patient 2 also demonstrates a stabilization of vascular disease in the left anterior descending coronary artery and the right coronary artery, as well as retardation of the course of vascular disease in the other coronary vessels. Patient No. 3 demonstrates a decrease in the progression of vascular disease in the coronary vasculature and carotid arteries following administration of the vitamin composition. Patient No. 6 received a physician's prescription of the vitamin composition recited in Example 1 in order to retard the course of vascular disease and to prevent or retard the onset of dementia and Alzheimer's disease. This patient was currently receiving a statin and aspirin. For at least all these reasons, Applicant respectfully asserts that evidence is provided in the specification that the claimed composition is effective in preventing vascular disease and in treating and preventing dementia. Accordingly, Applicant requests withdrawal of the rejection.

The office action further asserts that the specification fails to provide guidance in how to choose healthy subjects to whom the claimed composition should be administered, and fails to teach whether prevention is achieved for days, months or years. Applicant respectfully asserts that the patent application describes vascular disease as associated with many types of pathology including coronary artery disease, cerebrovascular disease and peripheral vascular disease. The application further describes on page 1 that vascular disease has been associated with dementia and other diseases of the nervous system including Alzheimer's disease (page 1, paragraph 2). Page 3 of the patent application teaches that the present invention includes methods of treating or preventing a vascular disease or dementia in an individual by administering a vitamin composition of the present invention. On page 3, paragraph 2, the specification teaches that various forms of dementia associated with vascular disease, such as Alzheimer's disease, may also be treated or prevented using the

vitamin compositions of the present invention. The methods of treating vascular disease or dementia in a human are further described on pages 13-15. Applicant respectfully asserts that in view of these teachings, one of ordinary skill in the art would readily ascertain whether an individual were at risk of vascular disease or dementia. One of skill in the art, for example a physician, could readily ascertain and weigh the significance of various risk factors for vascular disease, dementia and Alzheimer's disease. The present patent application discloses many of these risk factors and clearly states that vascular disease is associated with many of these conditions. For at least all the reasons recited above, Applicant respectfully asserts that the present invention does comply with enablement requirement and respectfully requests withdrawal of the rejection of claims 18-27 under 35 U.S.C. §112, first paragraph.

Rejection of claims 1-27 under 35 U.S.C. §102(b)

The office action rejects claims 1-27 under 35 U.S.C. §102(b) as being anticipated by Rowland (U.S. Patent No. 5,405,613), Paradissis et al. (U.S. Patent No. 5,494,678) or Jackson (U.S. Patent No. 6,040,333). Claims 15-17 and 23 are cancelled, rendering their rejection moot. Applicant respectfully asserts that this cited art does not disclose the compositions or methods recited in the amended claims. None of the art teaches the claimed composition consisting of vitamin B12, vitamin B6, folic acid, magnesium and vitamin E. Applicant respectfully asserts that the amendment overcomes the rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §102(b) and requests its withdrawal.

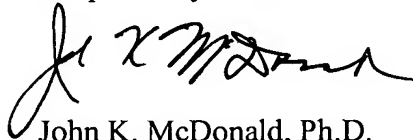
Rejection of claims 1-27 under 35 U.S.C. §103(a)

The office action rejects claims 1-27 under 35 U.S.C. §103(a) as being unpatentable over Rowland (U.S. Patent No. 5,405,613), Paradissis et al. (U.S. Patent No. 5,494,678) or Jackson (U.S. Patent No. 6,040,333) in combination with Horrobin et al. (U.S. Patent No. 6,369,041). Claims 15-17 and 23 are cancelled, rendering their rejection moot. Applicant's claim amendments render moot this rejection under 35 U.S.C. §103(a), as none of the cited

references alone, or in combination, suggest or provide motivation to one of ordinary skill in the art to derive Applicant's composition as now claimed. The cited art, alone or in combination, does not teach, suggest or provide motivation to derive the claimed composition consisting of vitamin B12, vitamin B6, folic acid, magnesium and vitamin E or its use in the recited methods. Applicant respectfully asserts that the amendment overcomes the rejection of claims 1-14, 18-22 and 24-27 under 35 U.S.C. §103(a) and requests its withdrawal.

Applicant's representative appreciates the courtesy of a telephone interview with Applicant's representative on June 1, 2005 and June 21, 2005. Applicant respectfully asserts that this response to the office action is timely filed and that the rejections delineated in the office action of March 31, 2005 have been overcome. If any informalities remain which may be discussed, a conference with the undersigned is respectfully requested. Further, if minor amendments may be achieved by Examiner's amendment, a call to the undersigned attorney is also respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John K. McDonald", is written over the typed name.

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